

REMARKS

Claim 1, 15 and 26 have been amended. Claims 6 and 27 have been cancelled. Claims 20-22 have been withdrawn. No new matter has been added. Thus, claims 1-5, 7-19 and 23-26 remain pending in the present application. It is submitted that, in view of the above-noted amendments and the following remarks, all of the presently pending claims are in condition for allowance.

Claims 1-5, 7-19 and 23-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Daly (U.S. Published Appln. No. 2004/0186444) in view of Twyman (U.S. Patent No. 2,755,060).

Amended claim 1 recites a valve apparatus comprising “first moveable elements [that] are maintained in a closed position in which no flow is permitted past the first flexible disk and, *when a pressure at least as great as the threshold value is applied to a planar face of the first flexible disk*, the first moveable elements are moved to an open position separated from one another along the at least one first slit permitting flow through the first lumen, *the first flexible disk further comprising at least one biasing member coupled thereto adjacent the first slit to increase a biasing force urging the first movable elements toward the closed position.*” Support for the amendment of claims 1, 15 and 26 can be found in paragraphs [0020], [0021], [0026] and [0029] of the Specification. Specifically, the Specification clearly describes “a pressure sensitive valve ... which opens in response to a pressure driving the flow through the catheter,” the valve being opened when “edges 120 of the movable elements 118 are moved out of the plane of the flexible disk 110.” (*Id.* at ¶ [0021], [0025]). It is therefore evident that the pressure flowing through the catheter can only be applied to a planar face of the slit valve to permit opening thereof.

Daly fails to teach or suggest a first flexible disk wherein “*when a pressure at least as great as the threshold value is applied to a planar face of the first flexible disk*, the first

moveable elements are moved to an open position separated from one another along the at least one first slit permitting flow through the first lumen, the first flexible disk further comprising at least *one biasing member coupled thereto adjacent the first slit to increase a biasing force urging the first movable elements toward the closed position*,” as recited in claim 1. The Examiner has affirmed this deficiency in Daly and cited Twyman to overcome this deficiency. (See 3/10/09 Office Action, p. 3). However, it is respectfully submitted that the member 18 of Twyman is explicitly configured to not be actuatable upon receipt of a fluid pressure but rather a radially compressive pressure. (See Twyman, col. 2, ll. 56-69). Specifically, the member 18 is formed of a semi-rigid sheet material that permits opening of the slit 16 only when compressor members 24, 26 located along a lateral periphery of the conduit are manually compressed to apply a radially compressive force to the member 18. (*Id.*, See Also col. 2, ll. 16-23; Figs. 2, 4-5). It is therefore respectfully submitted that Twyman also fails to teach a biasing member that urges movable elements of a flexible disk toward the closed position while still permitting flow therepast upon application of at least a threshold pressure to a planar face of the flexible disk. It is therefore submitted that employment of member 18 of Twyman in the Daly device still fails to overcome the limitation of a first flexible disk wherein “*when a pressure at least as great as the threshold value is applied to a planar face of the first flexible disk*, the first moveable elements are moved to an open position separated from one another along the at least one first slit permitting flow through the first lumen,” as recited in claim 1. Rather, as noted above, Twyman actually teaches away from such a member 18 that is permitted to open in response to a fluid pressure applied to a planar surface of the wall 14.

It is therefore respectfully submitted that both Daly and Twyman, taken alone or in combination, fail to teach or suggest a first flexible disk wherein “*when a pressure at least as great as the threshold value is applied to a planar face of the first flexible disk*, the first moveable elements are moved to an open position separated from one another along the at least one first slit permitting flow through the first lumen” in combination with “*the first flexible disk further comprising at least one biasing member coupled thereto adjacent the first slit to increase*

a biasing force urging the first movable elements toward the closed position,” as recited in claim 1. As also noted above, Daly and Twyman both teach away from such a modification. It is therefore respectfully submitted that claim 1 is in condition for allowance. Because claims 2-5 and 7-14 depend from and therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 15 recites limitations substantially similar to claim 1, including a dialysis connector comprising “moveable members being biased so that, *when a pressure less than a predetermined threshold value is applied to a planar face of the flexible disk, the moveable elements are maintained in a closed position* in which no flow is permitted past the flexible disk,” and “*biasing elements coupled to the flexible disk adjacent to the first slit to urge the moveable elements toward the closed position.*” It is therefore respectfully submitted that claim 15 is allowable over Daly and Twyman for the same reasons noted above with respect to claim 1. Because claims 16-19 and 23-25 depend from and therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Claim 26 also recites limitations substantially similar to claim 1, including a flow shutoff device comprising “movable elements being biased toward a closed position and being *movable to an open position when a pressure applied to a planar face of the valve exceeds a predetermined threshold value*” and “*at least one biasing member coupled thereto to increase a biasing force urging the movable elements toward the closed position.*” It is therefore respectfully submitted that claim 26 is allowable over Daly and Twyman for the same reasons noted above with respect to claim 1.

Claims 15-17 and 23-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith (U.S. Patent No. 4,244,379) in view of Twyman.

Smith fails to teach or suggest a “valve element including a flexible disk...being biased so

that...when a pressure at least as great as the threshold value is applied to the flexible disk, the movable elements are moved to an open position” in combination with a “*dialysis connector comprising a valve housing having a first end connectable to a patient line and a second end mounted to a dialysis line*; a flow passage of the housing being connected to the patient line and being operatively connectable to the dialysis line,” as recited in claim 15. It is noted that the above-recited limitation of claim 15 is a structural limitation that restricts a structure of the recited valve element to permit opening of the valve in both directions. Specifically, it is well known in the art that dialysis procedures require that fluids be withdrawn from *and* infused into the body. Thus, it is evident from the recitation of claim 15 that the “valve element” must be structured such that a connection thereof to a patient line and a dialysis line can facilitate dialysis (i.e., permit a two-way fluid flow therepast). Smith, on the other hand, is directed only to the withdrawal of blood from the body. (See Smith, col. 4, ll. 7-13). Specifically, Smith is directed to a one-way valve apparatus wherein the valve member 130 opens in response to a suction force applied from a direction opposite the backing member 140 to permit fluid withdrawal from the body. (See Smith, col. 5, ll. 34-57; Fig. 2). The valve member 130 of Smith device is inherently incapable of functioning in dialysis applications as it permits fluid flow in only one direction, specifically in the direction from the proximal needle 122 to the distal needle 128 to remove a fluid from the body. (*Id.* at col. 5, ll. 34-57, Fig. 2). Furthermore, as noted above, Smith is directed only to the withdrawal of blood from the body and explicitly recites the undesirability of injecting any blood into the body. (*Id.* at col. 5, ll. 34-39). Smith therefore fails to teach and further teaches away from a “*dialysis connector comprising a valve housing having a first end connectable to a patient line and a second end mounted to a dialysis line*; a flow passage of the housing being connected to the patient line and being operatively connectable to the dialysis line” in combination with “a valve element mounted within the flow passage of the housing,” as recited in claim 15.

Twyman fails to cure this deficiency in Smith. Specifically, employment of the member 18 of Twyman in the device of Smith would fail to permit two-way flow in the device of Smith.

It is therefore submitted that claim 15 is in condition for allowance.

Accordingly, it is submitted that Smith also fails to teach or suggest a “*dialysis connector comprising a valve housing having a first end connectable to a patient line and a second end mounted to a dialysis line; a flow passage of the housing being connected to the patient line and being operatively connectable to the dialysis line*” in combination with “a valve element mounted within the flow passage of the housing,” as recited in claim 15 and that claim 15 is therefore allowable over Smith. Because claims 16-17 and 23-25 depend from, and therefore include all of the limitations of claim 15, it is respectfully submitted that these claims are also allowable.

Amended claim 26 recites limitations substantially similar to claim 15, including “[a] *flow shutoff device for dialysis applications*, comprising: a housing attachable to a patient line; and a pressure actuated valve mounted within the housing to selectively restrict flow therethrough, the valve comprising a flexible disk including a plurality of movable elements separated by a slit extending through the disk [...], *the pressure actuated valve further comprising at least one biasing member coupled thereto to increase a biasing force urging the movable elements toward the closed position.*” It is therefore submitted that claim 26 is allowable over Smith for the same reasons stated above in regard to claim 15.

Claims 18-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Smith and Twyman in view of Jones (U.S. Patent No. 2,720,881).

Claims 18 and 19 depend from, and therefore includes all of the limitations of claim 15. As noted above, Smith and Twyman fail to teach the limitations of claim 15. Jones fails to cure this deficiency. Accordingly, it is submitted that claim 15 is allowable over Smith, Twyman and Jones, either alone or in combination. It is submitted that claims 18 and 19 are therefore allowable as dependent on an allowable base claim.

All issues raised by the Examiner having been addressed. Applicants therefore submit that the application is in condition for allowance.

Respectfully submitted,

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